Rev 4.0

ResMed Ventilators and COVID-19

Information on applications in the treatment of patients with COVID-19

The information contained in this document is current as of April 10, 2020, and is based on currently available information that will continue to change over time. The information in this guide with respect to treatment is believed to have a reasonable basis. ResMed assumes no obligation to update the information in this presentation, whether as a result of new information or future events.

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Executive Summary

As a medical technology manufacturer of respiratory devices, including ventilators, ResMed has mobilized a global task force in response to the COVID-19 pandemic. Our guiding principle in responding to the COVID-19 pandemic is the preservation of life throughout the world.

Access to critical care ventilators will be important during this pandemic and ResMed has taken the necessary steps to prioritize manufacturing resources for ventilators that support higher acuity patients. However, as ventilator resources become stretched due to high demand, alternative ventilation options such as non-invasive ventilation (NIV) bi-level and CPAP therapy will be crucial to stabilizing or sustaining patients who require respiratory support.

This document aims to assist governments and health authorities in understanding the application of ResMed's devices in providing ventilation support to patients with clinical syndromes due to COVID-19 infection. It is based on current information, which is changing rapidly and can be different in different regions – for specific regional guidance always refer to local published guidelines. **The purpose is not to direct clinical practice but to provide clear information on the available ResMed products and their application.**

Use of Ventilation for Patients with COVID-19

Patients affected by COVID-19 have a range of symptoms and varying degrees of severity of illness. All patients should be assessed thoroughly, with the decision to monitor a particular patient in the inpatient or outpatient setting depending on clinical presentation and severity of illness, the patient's ability to engage in monitoring, home isolation, and the risk of transmission.[1]

According to the Centers for Disease Control and Prevention (CDC), patients with mild illness on presentation may not initially require hospitalization; however, their symptoms may worsen with progression to lower respiratory tract disease.[1] Patients presenting with low oxygen saturation and increased respiratory rate will require oxygen supplementation, which can be delivered through a nasal cannula, mask or non-invasive ventilation. Those that fail to respond and subsequently develop hypoxemic respiratory failure or acute respiratory distress syndrome (ARDS) may require mechanical ventilation.[2]

Non-invasive ventilation is a form of mechanical ventilation where air is delivered to the patient through a mask or mouthpiece. **Invasive ventilation** is used when sufficient ventilation cannot be achieved using non-invasive methods so air is delivered through a tube inserted into the trachea either via intubation or tracheotomy.

Early data from China shows that 6% of patients with COVID-19 require ventilation,[3] with numbers rising to 89% for those in the intensive care unit (ICU).[4] Of these, 47.2% received invasive ventilation and 41.7% received non-invasive ventilation.[4] Emerging data from Italy, the epicenter of the COVID-19 outbreak in Europe, showed that 99% of patients with COVID-19 admitted to ICUs required respiratory support, of which 88% received invasive ventilation and 11% received non-invasive ventilation.[5]

Invasive ventilation is important for critically ill patients

Several guidance documents for the management of critically ill patients with COVID-19 have been published;[1, 2] these are by and large based on the usual management of viral pneumonia with respiratory failure, with additional precautions to reduce risk of transmission.

Current guidance from the World Health Organization (WHO) and others recommend early consideration for invasive ventilation for patients with severe COVID-19 who develop ARDS,[2, 6] and a strong preference for early use of invasive ventilation over non-invasive ventilation where appropriate and possible.[7] Additional information from the Handbook of COVID-19 Prevention and Treatment indicated that some severe patients progress to ARDS rapidly and intubation should be performed as early as possible if improvement in respiratory distress symptoms or PaO_2/FiO_2 is not observed.[8]

Evidently, access to invasive ventilators will be critical during this pandemic. However, the dramatic increase in patients requiring ventilator therapy may lead to ventilator scarcity. Emerging data from China show that only 25% of patients who died had received invasive ventilation, suggesting that ventilation resources may not have been available for critically ill patients.[9]

Non-invasive ventilation can be used to provide initial care for patients requiring respiratory support

In a discussion paper published on 5 March 2020, the U.S National Academy of Medicine indicated that the use of non-invasive ventilation therapy, such as continuous positive airway pressure (CPAP) or bi-level positive airway pressure (bi-level PAP), could be a way to forestall the need for intubation and reduce days on a ventilator.[10] Since then, there has been a growing evidence base on the significance of supplemental oxygen combined with either CPAP and bi-level PAP in the early stages of COVID-19, and in the prevention of further respiratory deterioration in patients with the disease.

CPAP is a non-invasive ventilation mode which provides a constant steady pressure to keep the lungs expanded. **Bi-level PAP** is a non-invasive ventilation mode that delivers two distinct pressures, one for inhalation and the second for exhalation; the change in pressures leads to flow of air in and out of the lungs. Most CPAP and bi-level PAP devices are compatible with supplementary oxygen, which can be entrained into the circuit or patient interface.

Governments and health administrations around the world have now issued guidance documents on the use of non-invasive ventilators, including CPAP and bi-level PAP devices, in patients with confirmed or suspected COVID-19.[11, 12] These guidelines are informed by published evidence, established clinical guidelines and case reports from clinicians in China and Italy, and recommend the use of non-invasive ventilation in the following scenarios:

1. When a patient needs support for respiratory insufficiency, but has not deteriorated into more severe hypoxemia, ARDS, or any other clinical scenario where invasive ventilation is more appropriate.[11, 12]

2. To facilitate extubation and recovery from invasive ventilation.[11] This will also allow an invasive ventilator to be cleaned and serviced and circulated back into use on another patient.
3. To shorten hospital stay, allowing patients who still need some respiratory support and rehabilitation[13] to transition to the home or non-hospital facilities.

Recently published treatment guidelines stress the need for clear escalation criteria or treatment ceilings when starting COVID-19 patients on non-invasive ventilation, in order to ensure patients are moved to invasive ventilation quickly if they are not responding or deteriorate quickly.[7,14] While non-invasive ventilation is not ideal for the most severe or critical cases of COVID-19, this therapy type is important in supporting triage, assisting with supplementary oxygen delivery in less severe cases and reducing reliance on invasive ICU ventilators. Additionally, for countries facing this public health emergency, and where hospital capacity is insufficient to meet demand, it will be important to support patients into the sub-acute or out-of-hospital care environments on non-invasive ventilation devices that are already used in millions of homes every day.

Adaptations to help bridge ventilator shortages

Guidance from governments

Health administrations around the world, recognizing the impending ventilator shortages, are working hard to prepare and deploy resources as quickly as possible. The European Commission launched several calls for tender in March 2020 for medical equipment and supplies, including non-invasive and invasive ventilation equipment.

The UK Medicines & Healthcare Products Regulatory Agency (MHRA) released a specification on 22 March 2020 for minimally clinically acceptable ventilator systems that are considered suitable for hospital use in treating COVID-19. This specification guidance outlines the need for pressure or volume controlled ventilation (pressure regulated volume control or pressure controlled ventilation) as well as bi-level devices while highlighting the monitoring and safety features expected of ventilators used in critical care situations.[15]

Recognizing the role that CPAP plays in the initial care of patients requiring respiratory support, the UK MHRA released a follow up specification on 29 March 2020 for minimally clinically acceptable CPAP systems to be used in UK hospitals during the current COVID-19 pandemic. This specification guidance highlights the need for oxygen compatibility and alarms for device failure or over pressure at the minimum.

The U.S. Food and Drug Administration (FDA) released an enforcement guidance on 22 March 2020 which provides a policy to help expand the availability of ventilators and other respiratory devices during this pandemic. The guidance describes the FDA's intention to exercise enforcement discretion for certain deviations, such as the use of ventilators outside their cleared environment of use, and the use of devices indicated for sleep apnea (including non-continuous ventilators delivering CPAP or bi-level positive airway pressure) to treat patients with respiratory insufficiency, provided that appropriate design mitigations are in place to minimize aerosolization.[16]

The World Health Organization (WHO) is in the midst of finalizing technical specifications for invasive and non-invasive ventilators in consultation with clinical experts and ventilator manufacturers. The final technical specifications will be published on the WHO COVID-19 site and is expected to support the procurement of ventilators during the COVID-19 pandemic.

Converting non-invasive ventilation devices for invasive use

Some advanced bi-level PAP devices are suitable for invasive ventilation and cleared in several jurisdictions for that use. However, in most European and North American countries, many bi-level devices are not cleared or approved by local regulatory authorities for use with intubation or tracheotomy because they lack alarms, sophisticated monitoring or modes, and their pressure generation is not sufficient to care for those with significant lung injury.

Given the anticipated shortage of mechanical ventilators in many countries, there have been calls for the use of bi-level PAP in intubated patients on an emergency basis. Evidence presented in a white paper by Syneos Health suggests that Volume Assured Pressure Support (VAPS), a mode available on newer bi-level devices, can in the right setting work as a bridge of support to deliver ventilation via an endotracheal tube until a conventional ventilator becomes available.[17] It should be noted, however, that the evidence available for this is limited and at best, rudimentary. If a bi-level PAP device is to be used in intubated patients for invasive ventilation, at minimum, a rigorous external monitoring system, with all of the functionality and alarms that are required for monitoring critically ill and mechanically ventilated patients, needs to be in place.

In the context of addressing the overwhelming demand for ventilators in the current pandemic, the American Association of Respiratory Care (AARC) has posted a video on their website to discuss the use of bi-level devices for invasive ventilation, including suggested circuit setup, humidification method, initial ventilation settings, and best practice for monitoring patients on these repurposed bi-level devices.[18]

Understanding that this application is likely to happen, ResMed is preparing advice for clinicians to improve patient safety when adapting ResMed bi-level devices for invasive use.

Ventilating multiple patients on a single ventilator

Noting the potential shortage of ventilators, there have been suggestions on the internet that purport ventilating multiple patients on a single ventilator. A joint statement issued by the AARC strongly advises clinicians against the sharing of ventilators as it could lead to poor outcomes and high mortality rates for all patients cohorted.[19]

Nonetheless, the U.S. Department of Health and Human Services (HHS) and the Federal Emergency Management Agency (FEMA) recognize that using one ventilator for two patients is a possible crisis standard-of-care strategy contemplated by many centres.[20] In an open letter published on the HHS website, the Assistant Secretary for Health and the U.S. Surgeon General advised that co-venting be considered only as an absolute last resort and for a limited amount of time.[20] An assembly of technical documents developed by academic leaders was published along with the letter to provide an example of the type of circuits, setups, and anticipated problems that one might face if this strategy was employed in a crisis care, life-or-death, situation.

The official statement from the FDA on co-venting is: *"FDA does not object to… ...placing more than one patient on mechanical ventilation when the number of patients who need invasive mechanical ventilation exceeds the supply of available ventilators and the usual medical standards of care has been changed to crisis care in the interest of preserving life. The FDA's no objection applies during the duration of the declared COVID–19 emergency."*[20] FDA is reviewing ventilators and associated accessories for co-venting as part of their Emergency Use Authorization (EUA).

Protecting healthcare workers to mitigate infection risk

Lessons from the 2003 SARS outbreak indicate that ventilation procedures exposes healthcare workers to infection risks. Of the invasive and non-invasive ventilation procedures assessed, performance of endotracheal intubation for invasive ventilation appeared to carry the highest risk of transmission.[21]

Some concerns have emerged regarding the risk of dispersion of aerosolized virus when utilizing non-invasive ventilation. However, evidence suggests that non-invasive ventilation procedures are more likely to produce large droplets (>10 µm) rather than aerosols, and that these are largely confined to within one meter due to their large mass.[22] This suggests that the risk of droplet dispersion as a result of use of non-invasive ventilation or bi-level devices may not be that different to that of any COVID-19 patient in the hospital who is coughing or sneezing.

Additionally, an experts' panel determined that non-invasive ventilation systems with a good interface fitting do not create widespread dispersion of exhaled air.[23] Recommendations have been published to support good mask fit to reduce aerosols, including use of full-face masks.[24] A recently published evidence-based comparison of official recommendations for infection control looked at the exhaled air dispersion from different oxygen therapy methods, concluding that CPAP via oronasal (full face) mask and non-invasive ventilation via helmet mask with an inflatable neck cushion are the ventilatory support methods that allow the minimum room air contamination.[25]

Nonetheless, the risk of aerosol dispersion needs to be mitigated with appropriate isolation of patients and the use of Personal Protective Equipment (PPE) for healthcare workers, such as gloves, disposable shirts, goggles, N95 masks/respirators and eye protection,[6, 25] which are now considered standard protective equipment in a COVID-19 ICU.[26,25] In addition, the use of appropriate and compatible expiratory valve filters for single-limb non-invasive ventilators may also help to reduce the risk of virus spread in the open patient room.

Recommended methods for reducing risk of virus spread include using suitable masks and filters, appropriate PPE and isolation techniques (see ***Figure 1***).

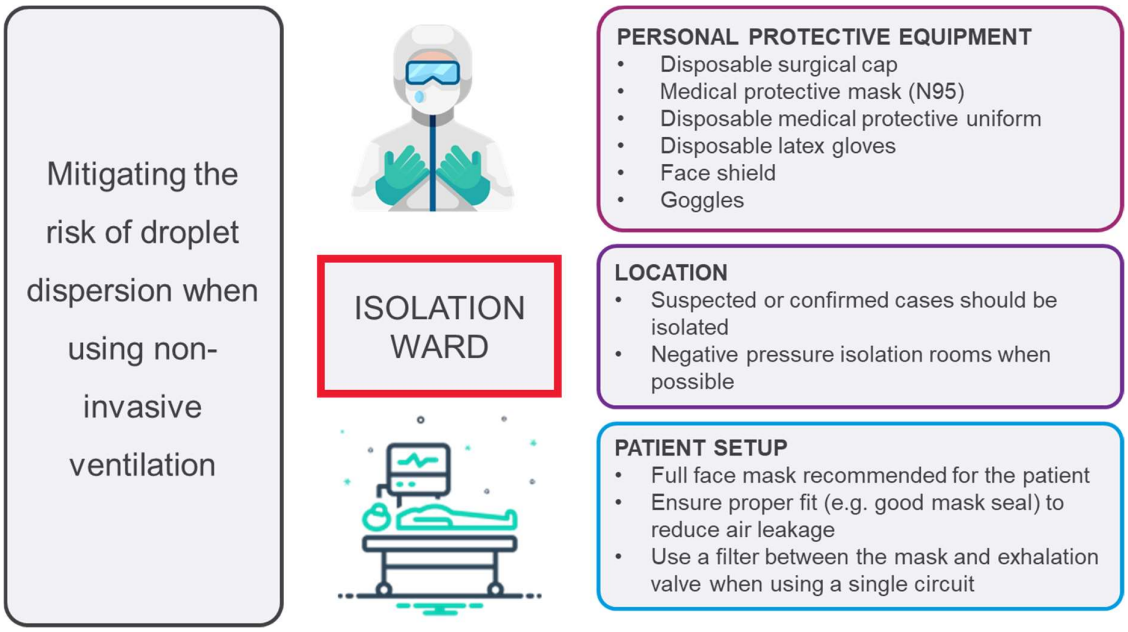

Figure 1. Mitigating risk of droplet dispersion when using non-invasive ventilation.[1, 8]

Clinical training for non-invasive ventilation

The principles of invasive ventilation and non-invasive ventilation are very similar, so training healthcare professionals (e.g. anesthesiologists, emergency physicians, intensivists, nurses, and respiratory therapists) who are well-versed in invasive ventilation to provide non-invasive ventilation should create few burdens. The two primary changes between invasive ventilation and non-invasive ventilation are the circuit configurations and the modes of ventilation utilized. There are fewer required circuit components when initiating non-invasive ventilation, so the burden is expected to be less than that of initiating invasive ventilation.

The most challenging part of setting up non-invasive ventilation is training caregivers to properly fit a mask. Poor mask fit can cause discomfort or intolerance, spread exposure to health care providers and reduce therapy effectiveness. The ability to anticipate, prevent and manage mask-related problems will be important for non-invasive ventilation success.

ResMed offers online tutorials of device setups, quick setup guides, suggested non-invasive ventilation settings and remote webinar trainings for users, all tools which largely allow for independent clinician setup of devices.

The method of ventilation is an important clinical decision to be made by the treatment team under rapidly evolving clinical guidelines for COVID-19 patients, availability of ventilation technology, clinical setting and availability of personal protective equipment for healthcare workers. The following information about ResMed devices is designed to assist and inform these decisions by clarifying applications and features of different devices.

ResMed Ventilators and Bi-level Devices – Application and Features

ResMed and Curative, a subsidiary of ResMed, manufactures a range of ventilators and bi-level devices. These devices are indicated for hospital and home use, and have the flexibility for use in various clinical scenarios (see ***Figure 2***). It should be noted, however, that these are **not** the same as ventilator equipment typically used in high acuity situations in hospital ICUs.

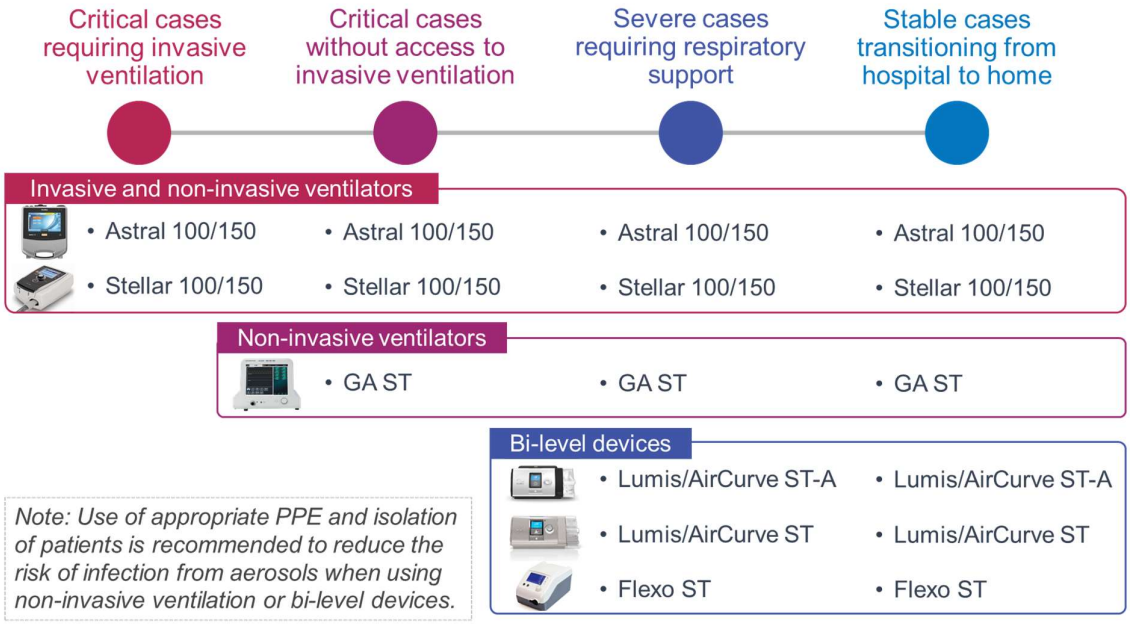

Figure 2. ResMed and Curative ventilators and bi-level devices in various clinical scenarios

The FDA in their COVID-19 ventilator enforcement guidance encourages applications to distribute in the U.S. ventilators and respiratory devices that have been approved in other jurisdictions;[16] this increases the ability of manufacturers like ResMed to respond.

The ResMed range of ventilators and bi-level devices capable of providing respiratory support to patients at various stages of dependency is shown below (see **Figure 3**).

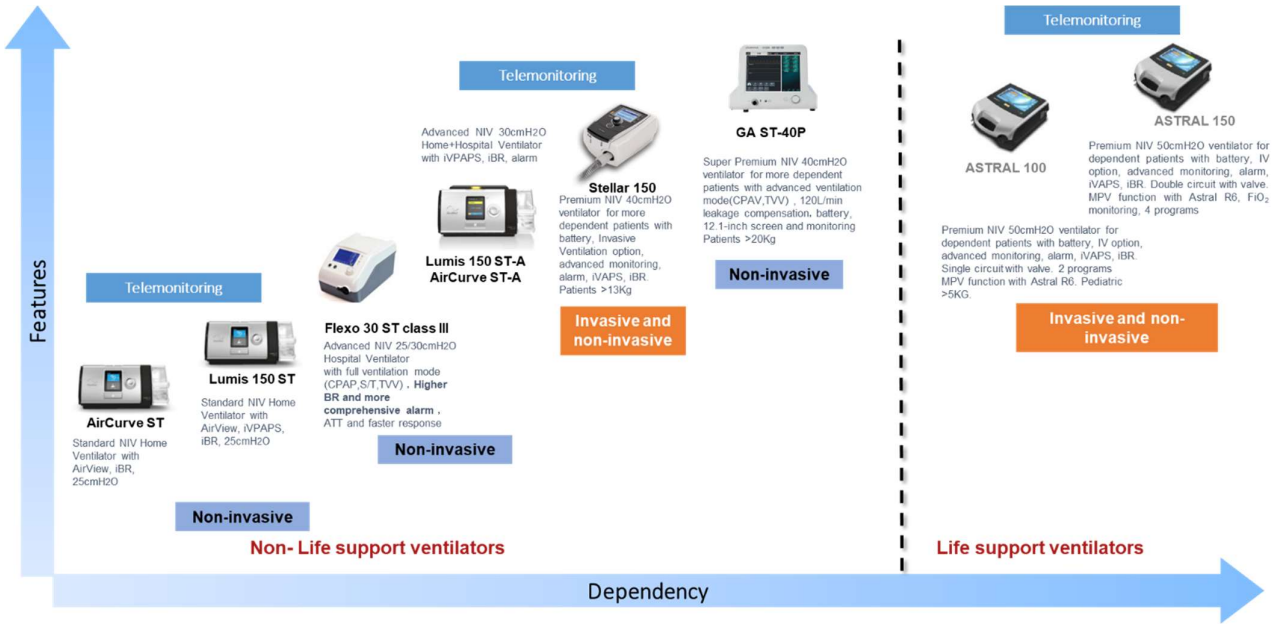

Figure 3. ResMed and Curative ventilators and bi-level devices

Invasive and non-invasive ventilators

Astral 100/150

Of the ResMed range of invasive and non-invasive ventilators, the Astral life-support ventilator provides the most comprehensive set of modes and settings and delivers both pressure and volume ventilation. The ResMed Astral 150 is the most comprehensive—it comes with all the standard features of the standard Astral 100 plus double limb circuit capabilities, which complements the use of an inspiratory and expiratory antibacterial/antiviral filter and a non-vented mask to reduce risk of contamination to healthcare professionals. The device allows addition of supplemental oxygen (no oxygen blender; low pressure oxygen only) at the air inlet up to 30L/min and provides monitoring of FiO_2. The ability to use an active circuit may help reduce particle spread. The device can generate higher pressures needed to care for an acutely ill patient. The option to have four pre-set settings may make it easier for less experienced staff taxed during the global health crisis to run the device. These devices also include remote monitoring that can facilitate “telehealth” or remote management of patients, as well as the ability to centralize telemonitoring of devices in a “war room” configuration

Stellar 100/150

The ResMed Stellar 100/150 is a non-invasive ventilator with invasive capabilities when combined with the ResMed leak valve, and is indicated for ventilation of non-dependent, spontaneously breathing patients. The Stellar 100/150 can be safely used in those recovering from acute lung injury such as ARDS or those with milder underlying lung disease. The device also allows addition of supplemental oxygen at the air inlet up to 30L/min and provides monitoring of FiO_2 with an additional FiO_2 monitoring

sensor attached. This device has an internal battery and can be used for transport within a hospital. Physicians consider this device a good option for step down units.

The Stellar 150 has been authorized for emergency use in healthcare settings in the U.S. to treat patients during the COVID-19 pandemic, subject to the conditions set forth in the FDA's Emergency Use Authorization (EUA).[27] The EUA for Stellar includes expanded warnings appropriate to critical care, including information on using Stellar 150 with an endotracheal tube. A list of ventilators authorized under the EUA can be found on the FDA website.[28]

Non-invasive ventilators

GA ST series

The GA ST series is a non-invasive ventilator indicated for ventilation of spontaneously breathing individuals. It is equipped with two oxygen input methods, high-pressure oxygen and low-pressure oxygen. The device allows addition of supplemental oxygen at the air inlet and is capable of providing up to 100% FiO_2. The maximum oxygen flow rate with low-pressure is 30 L/min. An oxygen mixer is also available for greater oxygen concentration accuracy. The use and replacement of the air inlet filter and main flow bacteria filter between patients and at regular intervals will reduce the risk of patient or ventilator contamination. This device is sold under the company name Curative, a ResMed family company.

Bi-level devices for non-invasive ventilation

Lumis and AirCurve

The Lumis and AirCurve range of ResMed devices[29] are bi-level devices indicated to provide non-invasive ventilation for patients with respiratory insufficiency. A "backup" rate can be set to ensure that patients still receive a minimum number of breaths per minute if they fail to breathe spontaneously. The ST-A variant comes with fixed and adjustable alarms to alert the user/caregiver in case of therapy issues and may be more appropriate for the ward environment than the ST variant, which is possibly more suitable for when a patient is discharged to a home environment. If necessary, supplemental oxygen up to 15 L/min can be connected to the air outlet of the Lumis and AirCurve range, but monitoring of FiO_2 is not done by the device. An additional oximetry adapter can be attached to measure SpO_2 if needed. These devices also include remote monitoring that can facilitate "telehealth" or remote management of patients, as well as the ability to centralize telemonitoring of devices in a "war room" configuration.

The European Lumis ST variant has been authorized for emergency use in healthcare settings in the U.S. to treat patients during the COVID-19 pandemic, subject to the conditions set forth in the FDA's EUA.[27] The EUA for Lumis includes expanded warnings appropriate to critical care.

Flexo ST series

The Flexo ST series is a bi-level device that provides non-invasive ventilator support for patients with respiratory insufficiency. Like the Lumis and AirCurve range, a timed backup mode allows the minimum number of breaths per minute to be set in the event that the patient slows or ceases respiratory efforts. The highest end of the Flexo ST series provides inspiratory pressures up to 30 cmH_2O and includes adjustable alarms to alert the user/caregiver in case of therapy issues. The Flexo device is not designed or intended to be used with supplemental oxygen. This device is sold under the company name Curative, a ResMed family company.

Summary of device specifications

Key specifications of ResMed ventilators and bi-level devices are provided in the table below (see ***Table 1***). Comprehensive information on these devices, their specific indications for use, modes and features is set forth in the Appendices.

Table 1. Key specifications of ResMed and Curative ventilators and bi-level devices

	Astral 100/150	Stellar 100/150	GA ST*	Lumis/AirCurve ST-A	Lumis/AirCurve ST	Flexo ST*
Invasive Capability	Yes	Yes (clinical bulletin released for endotracheal tube)	No	No	No	No
Non-invasive Capability	Yes	Yes	Yes	Yes	Yes	Yes
Max Pressure (cmH_2O)	50	40	40	30	25	30
O_2 Entry Location	Inlet	Inlet	Inlet	Outlet	Outlet	N.A.
Max O_2 Flow Rate (L/min)	30	30	30	15	15	N.A.
FiO_2 Monitoring/Alerts	Yes	Yes	Yes	No	No	No
Humidification	External	Integrated or External	External	Integrated or External	Integrated or External	External
Alarms	Yes	Yes	Yes	Yes	No	Yes
Internal battery	Yes	Yes	Yes	No	No	No
External battery	Yes	Yes	No	Yes	Yes	No
Telemonitoring	Yes	Yes	No	Yes	Yes	No
Modes	CPAP, (S)T, P(A)C, (A)CV, P(A)CV, P-SIMV, V-SIMV, PS, iVAPS	CPAP, S, ST (optional iBR),T, PAC, iVAPS	CPAP, S, T, ST, APCV, CPAV, TVV-t, TVV-ST, TVV-APCV	CPAP, S, ST (optional iBR), T, PAC, iVAPS	*AirCurve*: CPAP, S, ST, T *Lumis*: CPAP, S, ST (optional iBR),T, PAC, iVAPS	CPAP, S, T, ST, APCV, TVV

*GA ST and Flexo ST are devices offered by Curative, a subsidiary of ResMed.

Reprocessing of ResMed Devices

The novel coronavirus that causes the disease COVID-19, SARS-CoV-2, is an enveloped virus. Viruses of this type are susceptible to common disinfection methods. The U.S. Environmental Protection Agency has published a list of disinfectants that meets its criteria for use against SARS-CoV-2.[30] This authorized list of disinfectants is comprised of many commonly used disinfectants and is being actively updated as new information emerges.

Published guidance from health authorities reinforce the need to maintain standard cleaning and disinfection procedures.[31] For each ResMed device, these cleaning and disinfection procedures are provided in the device's associated clinical guide, user guide or service manual. To prevent cross-contamination, antibacterial filters should be used on air intake and circuits, and circuit accessories are to be replaced or sterilized. Instructions are also provided in the materials and method for cleaning surfaces.

References and Notes

Refer to local published guidelines for specific regional clinical guidance.

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APPENDIX– Device Specifications

Device availability will vary by region.

	Astral 100/150	Stellar 100/150	GA ST-40P*	Lumis 150 ST-A	AirCurve ST-A	Lumis 150 ST	AirCurve ST	Flexo ST30*
Indications for use	The Astral 100/150 devices provide continuous or intermittent ventilatory support for patients weighing more than 5 kg (11 lb) who require mechanical ventilation. The iVAPS mode with optional AutoEPAP is intended for patients weighing more than 30 kg (66 lb). The Astral device is intended to be used in home, institution/ hospital and portable applications for both invasive and non-invasive ventilation. The Astral device is not intended for use as an emergency transport ventilator.	The Stellar 100/150 is intended to provide ventilation for non-dependent, spontaneously breathing adult and paediatric patients (13kg/30 lb and above) with respiratory insufficiency, or respiratory failure, with or without obstructive sleep apnoea. The device is for noninvasive use, or invasive use (with the use of the ResMed Leak Valve).	The GA non-invasive ventilator is an assist ventilator and is intended to augment patient breathing. It is intended solely for spontaneously breathing individuals who require mechanical ventilation: patients with respiratory failure, chronic respiratory insufficiency, or obstructive sleep apnea in a hospital or other institutional settings under the direction of a physician. The ventilator is intended to support patients weighing 20 kg (44 lb) or greater	The Lumis 150 ST-A device is indicated to provide non-invasive ventilation for patients weighing more than 13 kg/30 lb or more than 30 kg/66 lb in iVAPS mode with respiratory insufficiency or obstructive sleep apnoea (OSA). It is intended for home and hospital use.	The AirCurve 10 ST-A is indicated to provide non-invasive ventilation for patients weighing more than 30 lb (13 kg) with respiratory insufficiency or obstructive sleep apnea (OSA). The AirCurve 10 ST-A is intended for home and hospital use.	The Lumis 150 VPAP ST device is indicated to provide non-invasive ventilation for patients weighing more than 13 kg/30 lb or more than 30 kg/66 lb in iVAPS mode with respiratory insufficiency or obstructive sleep apnoea (OSA). It is intended for home and hospital use.	The AirCurve 10 ST device is indicated for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 66 lb (30 kg). It is intended for home and hospital use.	Flexo Bi-level positive airway pressure therapy device is used to provide non-invasive ventilatory support of mechanical ventilation for • Patients who are independent and spontaneously breathing • Patients with respiratory insufficiency and sleep breathing disorders It can provide both a stable continuous positive airway pressure and a bi-level positive airway pressure. It is not a life support ventilator. It is intended to be used in the home or professional medical environment.
Device Type	Mechanical ventilator for life support	Mechanical ventilator non-life support	Mechanical ventilator non-life support	Bi-level/BiPAP with alarms	Bi-level/BiPAP with alarms	Bi-level/BiPAP	Bi-level/BiPAP	Bi-level/BiPAP

	Astral 100/150	Stellar 100/150	GA ST-40P*	Lumis 150 ST-A	AirCurve ST-A	Lumis 150 ST	AirCurve ST	Flexo ST30*
Patient Weight	>5 kg (all modes except iVAPS)	≥13 kg (all modes except iVAPS)	≥20 kg	>13 kg (all modes except iVAPS)	>13 kg (all modes except iVAPS)	>13kg (all modes except iVAPS)	>30kg	-
	>30 kg (iVAPS)	≥30 kg (iVAPS)		≥30 kg (iVAPS)	≥30 kg (iVAPS)	≥30kg iVAPS		
Ventilation Delivery Specifications								
Patient Interface	non-invasive	non-invasive	non-invasive	non-invasive	non-invasive	non-invasive	non-invasive	non-invasive
	invasive	Invasive (with the use of ResMed leak valve)						
Circuit Type	Single valve	single leak	single leak	single leak	single leak	single leak	single leak	single leak
	Single leak							
	Double							
Pressure or Volume cycled	Pressure	Pressure	Pressure	Pressure	Pressure	Pressure	Pressure	Pressure
	Volume							
Operating Pressure Range	2-50 cmH_2O: (S)T, P(A)C, iVAPS	2-40 cmH_2O: S, ST, T, PAC, iVAPS	4-40 cmH_2O	2 - 30 cmH_2O: S, ST, T, PAC, iVAPS	3-30 cmH_2O: S, ST, T, PAC, iVAPS	2-25 cmH_2O: S, ST, T, PAC, iVAPS	3-25 cmH_2O: S,ST, T	4-30 cmH_2O: S, T, ST, APCV
	3-20 cmH_2O: CPAP	4-20 cmH_2O: CPAP		4-20 cmH_2O: CPAP	4-20 cmH_2O: CPAP	4-20 cmH_2O: CPAP	4-20 cmH_2O: CPAP	4-20 cmH_2O: CPAP
	0-50 cmH_2O: PS, P-SIMV, V-SIMV							
Therapy Modes	CPAP, (S)T, P(A)C, (A)CV, P(A)CV, P-SIMV, V-SIMV, PS, iVAPS	CPAP, S, ST (optional iBR),T, PAC, iVAPS	CPAP, S, T, ST, APCV, CPAV, TVV-t, TVV-ST, TVV-APCV	CPAP, S, ST (optional iBR), T, PAC, iVAPS	CPAP, S, ST (optional iBR), T, PAC, iVAPS	CPAP, S, ST (optional iBR),T, PAC, iVAPS	CPAP, S, ST, T	CPAP, S, T, ST, APCV, TVV
Performance Specifications								
Pressure Support Range	-	0-38 cmH_2O	0-38 cmH_2O	0-28 cmH_2O	0-27 cmH_2O	0-23 cmH_2O	0-22 cmH_2O	0-26 cmH_2O
		0-30 cmH_2O (in iVAPS mode)						
Intended Volume Range	Adult: 100 - 2,500 mL, Paed: 50 - 300 mL: (A)CV, V-SIMV	50-3000 mL	200-2000 mL	100–2500 mL	100-2500 mL	100-2500 mL	100-2500 mL	50-2500 mL
Supplementary Oxygen – Max Flow	30 L/min	30 L/min	30 L/min	15 L/min (S, ST, T, PAC, CPAP)	15 L/min (S, ST, T, PAC, CPAP)	15 L/min (S, ST, T, PAC, CPAP)	15 L/min (S, ST, T)	n/a
				4 L/min (iVAPS)	4 L/min (iVAPS)	4 L/min (iVAPS)		

	Astral 100/150	Stellar 100/150	GA ST-40P*	Lumis 150 ST-A	AirCurve ST-A	Lumis 150 ST	AirCurve ST	Flexo ST30*
Supplementary Oxygen – where to add	Device oxygen inlet	Device oxygen inlet	Device oxygen inlet	Device air outlet (eg. Side port of ClimateLineAir Oxy tube), mask	Device air outlet (eg. Side port of ClimateLineAir Oxy tube), mask	Device air outlet (eg. Side port of ClimateLineAir Oxy tube), mask	Device air outlet (eg. Side port of ClimateLineAir Oxy tube), mask	n/a
SpO2 measurement	Optional accessory	Optional accessory	Optional accessory	Optional accessory	Optional accessory	Optional accessory	Optional accessory	n/a
FiO2 monitoring	Optional accessory	Optional accessory	Optional accessory	n/a	n/a	n/a	n/a	n/a
Internal Battery Runtime	8 hours (a new battery under normal conditions)	3 hours (a new battery under normal conditions)	4 hours	n/a	n/a	n/a	n/a	n/a
	Lithium-Ion battery, 14.4 V, 6.6 Ah, 95 Wh	Lithium-Ion battery, 14.4 V, 2.75 Ah, 40 Wh						
Humidification	External	Integrated or External	External	Integrated or External	Integrated or External	Integrated or External	Integrated or External	External
Safety								
Max single fault pressure	90 cmH_2O	60 cm H_2O (in all modes)	-	30 cmH_2O for >6 s, or	30 cmH_2O for >6 s, or	30 cmH_2O for >6 s, or	30 cmH_2O for >6 s, or	-
				40 cmH_2O for >1 s	40 cmH_2O for >1 s	40 cmH_2O for >1 s	40 cmH_2O for >1 s	
Design Life	Device: 8 years	Device: 5 years	Device: 10 years	Device, PSU: 5 years	Device, PSU: 5 years	Device, PSU: 5 years	Device, PSU: 5 years	Device: 5 years
		Air Tubing: 6 months		Cleanable Humidifier: 2.5 years	Cleanable Humidifier: 2.5 years	Cleanable Humidifier: 2.5 years	Cleanable Humidifier: 2.5 years	
				Air Tubing: 6 months	Air Tubing: 6 months	Air Tubing: 6 months	Air Tubing: 6 months	
Alarms	Total power failure	Power fail	High/low pressure	Power fail	Power fail	n/a	n/a	Patient circuit disconnect
	Circuit disconnection	Blocked tube	High/low oxygen pressure	Blocked tube	Blocked tube			
	Low Pressure, High Pressure	Tube disconnected, System fault	No oxygen supply	Tube disconnected	Tube disconnected			High inspiratory pressure
	Obstruction	High temperature, Internal battery low/empty	High/low inspiratory pressure	High leak	High leak			

	Astral 100/150	Stellar 100/150	GA ST-40P*	Lumis 150 ST-A	AirCurve ST-A	Lumis 150 ST	AirCurve ST	Flexo ST30*
	Apnea	Over pressure	Patient circuit disconnection	Non-vented mask	Non-vented mask			Apnea
	Low / High MVe , Low / High MVi	High leak	Low/failed internal battery	Apnea	Apnea			
	Low / High Vte, Low / High Vti	Non-vented mask	Internal battery powering	Low SpO2 (when oximeter connected)	Low SpO2 (when oximeter connected)			Low tidal volume
	Low / High Resp rate	Low minute ventilation	external battery powering	Low minute ventilation	Low minute ventilation			
	High leak	Apnea	Power return	System fault	System fault			Low minute volume
	Ventilation stopped	High/Low pressure	Tube disconnected					
	Low / High SpO_2	High/Low respiratory rate,	High extremity pressure					High/low leak
	Low / High pulse rate	High/Low FiO_2	High/low external battery voltage					
	Low / High FiO_2	Low SpO_2	Pressure sensor failure					
	NV mask/Rebreathing		Communication error with main board					
	Incorrect circuit adapter		Cooling fan speed too low					
	Critically low battery		Blocked airway path					
	Incorrect circuit attached		High/low leak					
	Safety reset complete		Apnea					
	Battery inoperable		Low MV					
	Low / High PEEP		High/low BPM					
	Device overheating		High/low VT					
	Pressure line disconnected		High/low TVV					
	Self-test failed							
	Flow sensor not calibrated							

	Astral 100/150	Stellar 100/150	GA ST-40P*	Lumis 150 ST-A	AirCurve ST-A	Lumis 150 ST	AirCurve ST	Flexo ST30*
	No SpO2 monitoring							
	No FiO2 monitoring							
	Internal battery degraded							
	Low internal battery							
	Circuit fault							
	Using internal battery							
	Battery 1 fault, Battery 2 fault							
	Power fault/No charging							
	PEEP blower failure							
	System Fault alarms							
Environmental								
Operating Temperature	32°F to 104°F (0°C to 40°C)	+32°F (0°C) to + 95°F (35°C)	+5°C to +40°C	+41°F to +95°F (+5°C to +35°C)	+41°F to +95°F (+5°C to +35°C)	+41°F to +95°F (+5°C to +35°C)	+41°F to +95°F (+5°C to +35°C)	+5°C to +35°C
Operating Humidity	5 to 93% non-condensing	10%–95% non-condensing	10 to 93% non-condensing	10 to 95% relative humidity, non-condensing	10 to 95% relative humidity, non-condensing	10 to 95% relative humidity, non-condensing	10 to 95% relative humidity, non-condensing	10%–95% non-condensing
Storage and Transport Temperature	-13°F to 158°F (-25°C to 70°C)	-4°F (-20°C) to +140°F (60°C)	-20°C to +55°C	-4°F to +140°F (-20°C to +60°C)	-4°F to +140°F (-20°C to +60°C)	-4°F to +140°F (-20°C to +60°C)	-4°F to +140°F (-20°C to +60°C)	-20°C to +55°C
Storage and Transport Humidity	5 to 93% non-condensing	10%–95% non-condensing	10 to 93% non-condensing	5 to 95% relative humidity, non-condensing	5 to 95% relative humidity, non-condensing	5 to 95% relative humidity, non-condensing	5 to 95% relative humidity, non-condensing	10%–95% non-condensing

*GA ST and Flexo ST are devices offered by Curative, a subsidiary of ResMed.